

REMARKS / ARGUMENTS

I. Amendments to the specification and claims

The passage at page 17 line 7 to page 18 line 13 is amended from past tense to the present tense. Applicants clarify that this passage describing the immunization in mice and *C. pneumoniae* challenge is a prophetic description. This is made explicit by amendment of this passage to the present tense.

Claims 18, 19 and 39 are cancelled without prejudice or disclaimer. Claims 81-83 are added. Claims 1-17, 20-38 and 79-83 are pending in this application.

Claims 1, 3, 20 and 21 are amended to recite --An isolated-- nucleic acid or polypeptide. The amendment finds basis in the specification at page 11, lines 14-27.

Claims 8 and 9, and claims depended thereon, are amended to be drawn to --A vaccine vector comprising at least one nucleic acid-- rather than to "An immunogenic composition comprising a vaccine comprising a vaccine vector and at least one nucleic acid".

The claims are amended throughout to delete recitation of sequences having percent identities to a reference sequence.

Claims 79 and 80 are amended to delete, respectively, parts (c) and (d), and parts (ii) and (iv), which now appear in new claims 81 and 82. New claim 83 is a dependent claim which recite the further limitation that --the at least one nucleic acid is operably linked to a viral promoter functional in a mammalian cell--. Basis for this amendment is found at least at page 30, line 31 to page 31, line 6.

Because these amendments and new claims do not introduce new matter, entry thereof by the Examiner is respectfully requested.

Applicants retain the right to present claims drawn to the cancelled subject matter in a divisional application(s).

II. Election/Restriction

A Petition to have the Commissioner reconsider the Decision on Petition for Review of Restriction Requirement is being submitted concurrently with this Response.

In the Decision, the Commissioner states that Griffais (U.S. Patent No. 6,559,294) has a filing date before the filing date of the instant application's oldest priority application and is novelty-destroying. The Commissioner states that accordingly, the technical feature of linking groups I-VII does not constitute a special technical feature as defined by PCT Rule 13.2, and hence unity of invention is lacking.

Applicants submit a Declaration under 37 CFR § 1.131 of inventor Andrew Murdin. Dr. Murdin declares he had possession of the polypeptide of SEQ ID No:14 and nucleic acids encoding SEQ ID No:14 before Griffais' filing date (November 4, 1998).

Applicants invented the invention before Griffais. U.S. Patent No. 6,559,294 is not prior art. The technical feature of linking groups I-VII does constitute a special technical feature as defined by PCT Rule 13.2 and does define a contribution over the prior art. There is unity present.

The Examiner is requested to withdraw the restriction requirement set forth in the Decision mailed January 13, 2004 and is respectfully urged to examine all pending claims 1-17, 20-38 and 79-83.

III. Rejection Under 35 U.S.C. § 112, First Paragraph (Written Description)

The Examiner rejects claims 1-19, 36, 38(a), 79 and 80, alleging that the specification does not reasonably convey that Applicants have possession of the invention at the time the application was filed.

The Examiner states “With the exception of an isolated polynucleotide comprising SEQ ID NO:1 and an isolated polynucleotide comprising a nucleotide sequence encoding SEQ ID NO:14, fragments thereof and associated vectors, vaccines, fusions etc. dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation.”

Applicants traverse.

The claims are amended to delete reference to sequences having 75% identity to SEQ ID NO:14. All that remains relates to isolated polynucleotides comprising SEQ ID NO:1 or comprising a nucleotide sequence encoding SEQ ID NO:14, fragments thereof and associated vectors, vaccines, fusions etc. dependent thereon. The claims as amended comply with the written description requirement of 35 U.S.C. §112, First Paragraph and the rejection should be withdrawn.

IV. Rejection Under 35 U.S.C. § 112, First Paragraph (Enablement)

The Examiner rejects claims 1-19, 36, 38(a), 79 and 80, alleging that the specification, while enabling for an isolated polynucleotide comprising SEQ ID NO:1, DNA encoding SEQ ID NO:14, vector comprising said nucleic acid, and host cell comprising said vector, does not reasonably provide enablement for nucleic acid encoding immunogenic fragments or polypeptides having 75% identity to SEQ ID NO:14. Applicants traverse.

The claims are amended to delete reference to sequences having 75% identity to SEQ ID NO:14. All that remains relates to isolated polynucleotides comprising SEQ ID NO:1 or comprising a nucleotide sequence encoding SEQ ID NO:14, fragments thereof and associated vectors, vaccines, fusions etc. dependent thereon.

The Examiner states that “The state of the prior art indicates that protein chemistry is probably one of the most unpredictable areas of biotechnology” and that “The art teaches that even a *single amino acid change* in a protein leads to unpredictable changes in the *biological activity* of the protein.” [emphasis added].

First, Applicant points out that the instant specification is not concerned with the biological activity of the protein. Rather, the specification describes the claimed nucleic acids and polypeptides in terms of their utility as immunogenic compounds. As pointed out in the response filed June 27, 2003, it is a matter of routine to generate an immune response to peptides of 6 to 15 amino acids. This is evident by the number of groups offering to produce anti-peptide antibodies as a commercial service from the various Web sites.

Secondly, Applicant points out that the claims as amended recite nucleic acids encoding SEQ ID NO:14 and fragments thereof. The claims no longer recite % identity variants. Other than the fact that the fragment sequences are shorter than SEQ ID NO:14, there is no change in the amino acid sequence. Thus there is no unpredictable change to the utility of the sequences being claimed.

The Examiner is requested to reconsider and withdraw the rejection under the enablement provision of 35 U.S.C. § 112, First Paragraph.

V. Rejection of the Claims Under 35 U.S.C. § 102(b)

The Examiner rejects claims 18 and 19 as being anticipated by various commercial catalogs disclosing random primers and probes. Claims 18 and 19 are canceled, thereby rendering the rejection moot.

VI. Rejection of the Claims Under 35 U.S.C. § 102(e) -- US patent 6,559,294 ('Griffais')

The Examiner rejects claims 1, 2, 8, 16, 38, 79 and 80 under 35 U.S.C. 102(e) as being anticipated by Griffais. Applicants traverse.

Attached is a Declaration under 37 CFR § 1.131 of inventor Andrew Murdin. Dr. Murdin declares he had possession of the polypeptide of SEQ ID NO:14 and nucleic acids encoding SEQ ID NO:14 before Griffais' USC 102(e) date (November 4, 1998).

Withdrawal of the rejection under 35 U.S.C. §102(e) in view of Griffais is requested.

VII. Concluding Remarks

In view of the above amendments and remarks, reconsideration and favorable action on all pending claims are respectfully requested. If any questions or issues remain, the Examiner is invited to contact the undersigned at the telephone number set forth below so that a prompt disposition of this application can be achieved.

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If a fee is required for an extension of time which is not accounted for, such an extension is requested and the U.S.P.T.O. is authorized to withdraw from our Deposit Account Number 19-0741 any fee required.

Respectfully submitted,

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